



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft National Toxicology Program Monograph on Immunotoxicity Associated with Exposure to Perfluorooctanoic Acid or Perfluorooctane Sulfonate; Availability of Document; Request for Comments; Notice of Meeting

SUMMARY: The notice announces a meeting to peer review the draft NTP monograph on immunotoxicity associated with exposure to perfluorooctanoic acid (PFOA) or perfluorooctane sulfonate (PFOS). The Office of Health Assessment and Translation, Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), prepared the draft NTP monograph. The peer review meeting is open to the public. Registration is requested for both public attendance and oral comment and required to access the webcast. Information about the meeting and registration are available at <http://ntp.niehs.nih.gov/go/36639>.

DATES:

Meeting: July 19, 2016, 9:00 AM to approximately 2:00 PM Eastern Daylight Time (EDT).

Document Availability: The draft NTP monograph should be available by June 7, 2016, at <http://ntp.niehs.nih.gov/go/36639>.

Written Public Comment Submission: Deadline is July 5, 2016.

Registration for Oral Comments: Deadline is July 12, 2016.

Registration for Meeting and/or to View Webcast: Deadline is July 19, 2016. Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting Webpage: The draft NTP monograph, preliminary agenda, registration, and other meeting materials will be available at <http://ntp.niehs.nih.gov/go/36639>.

Webcast: The URL for viewing webcast will be provided to those who register.

FOR FURTHER INFORMATION CONTACT: Dr. Yun Xie, NTP Designated Federal Official, Office of Liaison, Policy, and Review, DNTP, NIEHS, P.O. Box 12233, MD K2-03, Research Triangle Park, NC 27709. Phone: (919) 541-3436, Fax: (301) 451-5455, Email: yun.xie@nih.gov. Hand Delivery/Courier: 530 Davis Drive, Room 2161, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background on PFOA and PFOS: PFOA and PFOS are persistent chemicals that are widely distributed in the environment, in part because of high stability and little to no expected degradation in the environment. PFOA and PFOS have been used extensively over the last 50 years in commercial and industrial applications, including food

packaging, lubricants, water-resistant coatings, and fire-retarding foams. Through voluntary agreements, the primary manufacturer of PFOS phased out production in 2002, and PFOS is no longer manufactured in the United States. Similar arrangements have been made for PFOA, and eight companies that manufacture PFOA committed to eliminate emissions and product content by 2015. Although emissions have been dramatically reduced, the persistence and bioaccumulation of both PFOA and PFOS result in detectable levels in the U.S. population and, therefore, these chemicals are of potential human health relevance. Several recent publications from 2012-2014 have linked PFOA and PFOS exposure to functional immune changes in humans, which are consistent with evidence of PFOA- and PFOS-related immunotoxicity in animal studies.

NTP has conducted a systematic review of the evidence for an association between exposure to PFOA or PFOS and immunotoxicity or immune-related health effects. The NTP evaluation concept for immunotoxicity associated with exposure to PFOA or PFOS was presented and discussed at the NTP Board of Scientific Counselors (BSC) meeting on December 10, 2014 (79 FR 62640). The NTP evaluation concept, related presentation, and BSC meeting minutes are available at <http://ntp.niehs.nih.gov/go/9741>. The protocol for conducting this systematic review is available at <http://ntp.niehs.nih.gov/go/749926>.

Meeting and Registration: The meeting is open to the public with time set aside for oral public comment. Please note that this will be both an in-person and web-based meeting. The chair of the peer review panel and NTP staff will be at the meeting location at NIEHS. The peer review panel members will be attending the meeting via web-based

video conferencing. Public attendees are welcome to watch the meeting via webcast or attend in person. Attendance at NIEHS is limited only by the space available.

Registration to attend the meeting in-person or to view the webcast is by July 19, 2016, at <http://ntp.niehs.nih.gov/go/36639>. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Visitor and security information for those attending in-person is available at <http://www.niehs.nih.gov/about/visiting/index.cfm>. Individuals with disabilities who need accommodation to participate in this event should contact Dr. Yun Xie at phone: (919) 541-3436 or email: yun.xie@nih.gov. TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

The preliminary agenda and draft NTP monograph should be posted on the NTP website (<http://ntp.niehs.nih.gov/go/36639>) by June 7, 2016. Additional information will be posted when available or may be requested in hardcopy, see FOR FURTHER INFORMATION CONTACT. Following the meeting, a report of the peer review will be prepared and made available on the NTP website. Individuals are encouraged to access the meeting webpage to stay abreast of the most current information regarding the meeting.

Request for Comments: The NTP invites written and oral public comments on the draft NTP monograph. The deadline for submission of written comments is July 5, 2016, to enable review by the peer review panel and NTP staff prior to the meeting. Registration to provide oral comments is by July 12, 2016, at <http://ntp.niehs.nih.gov/go/36639>. Public

comments and any other correspondence on the draft NTP monograph should be sent to the FOR FURTHER INFORMATION CONTACT. Persons submitting written comments should include their name, affiliation, mailing address, phone, email, and sponsoring organization (if any) with the document. Written comments received in response to this notice will be posted on the NTP website according to NTP's guidelines for public comments (http://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf), and the submitter will be identified by name, affiliation, and/or sponsoring organization if applicable.

Public comment at this meeting is welcome, with time set aside for the presentation of oral comments on the draft NTP monograph. Guidance for oral public comments is available at http://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf. In addition to in-person oral comments at NIEHS, public comments can be presented by teleconference line. There will be 50 lines for this call; availability is on a first-come, first-served basis. The lines will be open from 9:00 AM until approximately 2:00 PM EDT on July 19, 2016, although oral comments will be received only during the formal public comment periods indicated on the preliminary agenda. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Each organization is allowed one time slot. At least 7 minutes will be allotted to each time slot, and if time permits, may be extended to 10 minutes at the discretion of the chair.

Persons wishing to make an oral presentation are asked to register online at <http://ntp.niehs.nih.gov/go/36639> by July 12, 2016, and indicate whether they will

present comments in-person or via the teleconference line. If possible, oral public commenters should send a copy of their slides and/or statement or talking points at that time. Written statements can supplement and may expand the oral presentation. Registration for in-person oral comments will also be available at the meeting, although time allowed for presentation by on-site registrants may be less than that for registered speakers and will be determined by the number of speakers who register on-site.

Background Information on OHAT: OHAT was established to serve as an environmental health resource to the public and regulatory and health agencies (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3094430>). This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as “substances”) cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. OHAT also organizes workshops or state-of-the-science evaluations to address issues of importance in environmental health sciences. Information about OHAT is found at <http://ntp.niehs.nih.gov/go/ohat>.

Background Information on NTP Peer Review Panels: NTP panels are technical, scientific advisory bodies established on an "as needed" basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and

providing information to regulatory agencies about alternative methods for toxicity screening. The NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide current curriculum vitae to the FOR FURTHER INFORMATION CONTACT. The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service (PHS) Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: February 22, 2016

John R. Bucher, Ph.D.

Associate Director, NTP

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